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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,651	08/30/2000	Michael Lassner	MTC 6718	1981

7590 12/16/2004

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/651,651	LASSNER ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-120* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/30/2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/03/01; 6/29/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence attachments 1&2*.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-4, 8-9, 12-21, 24-25, 27, 29, 31, 33, 35, 37, 39, 51-75, 79-81, 83, 85, 87, 89-106, 109-110, 112, 114, 116 and 118-120.

Continuation of Disposition of Claims: Claims rejected are 1-2,5-7,10-11,22-23,26,28,30,32,34,36,38,40-5076-78,82,84,86,88,107,108,111,113,115,117.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-2, 5-19, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115 and 117 in the reply filed on 9/20/2004 is acknowledged. Claims 22 and 23, drawn to a recombinant construct comprising a polynucleotide encoding a lecithin:cholesterol acyltransferase-like polypeptide were inadvertently omitted from Group I and will be examined with elected Group I and elected polynucleotide sequence SEQ ID NO: 4.

Claims 1-120 are pending. Claims 3-4, 8-9, 12-21, 24-25, 27, 29, 31, 33, 35, 37, 39, 51-75, 79-81, 83, 85, 87, 89-106, 109-110, 112, 114, 116 and 118-120 are withdrawn as being drawn to non-elected Groups II-VII or non-elected polynucleotide sequences other than SEQ ID NO: 4. Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115 and 117 are examined.

Drawings

The drawings are objected to because Figure 5 does not clearly distinguish control, napin LCAT1, or napin LCAT3 transformants from each other. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and

appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On pages 3-8 of the specification, Applicant recites the formula 5'X-$(R_1)_n$-$(R_2)_n$-$(R_3)_n$-Y3', and defines R_2 as any nucleotide and then states that R_2 is a nucleotide sequence selected from a particular group. Further, Applicant does not indicate what is R_3. Appropriate correction is required.

Claim Objections

Claims 5-7, 32, 40, 48, 78 and 113, are objected to because of the following informalities: Claims 5-7, 32, 40, 43 and 113 recite non-elected polynucleotide or polypeptide sequences and Claims 48 and 78 recite a dependency to a non-elected claim. Appropriate correction is required.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: in the Brief Description of the Drawings beginning on page 9 of the

specification does not reference the non-plant LCAT sequences and plant LCAT sequences using sequence identifiers and does not indicate which vectors contain which sequence identifiers.

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115 and 117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims an isolated nucleic acid sequence comprising a polynucleotide encoding a plant lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof; an isolated polynucleotide having at least 70% sequence identity to SEQ ID NO: 4; an isolated polynucleotide having at least 10 nucleotides that hybridize under condition of unspecified stringency to SEQ ID NO: 4; an isolated polynucleotide encoding SEQ ID NO: 5 with at least

one conservative amino acid substitution; an isolated polynucleotide that hybridizes to SEQ ID NO: 4 under conditions of unspecified stringency and encodes a plant lecithin:cholesterol acyltransferase-like polypeptide; an isolated nucleic acid sequence consisting of a polynucleotide having the formula 5'X-$(R_1)_n$-$(R_2)_n$-$(R_3)_n$-Y3', a recombinant construct comprising a regulatory sequence operably linked to a sequence encoding a lecithin:cholesterol acyltransferase-like polypeptide and host cells, plants and progeny and seeds transformed therewith.

Applicant describes a polynucleotide from human of SEQ ID NO: 1 encoding a lecithin:cholesterol acyltransferase (i.e. LCAT); LCAT1, LCAT2, LCAT3 from *Arabidopsis* identified from GenBank accessions AC00457, AC003027, and AL024486 comprising polynucleotides of SEQ ID NO: 2, 4 and 6 encoding lecithin:cholesterol acyltransferase-like polypeptides of SEQ ID NO: 3, 5 and 7 respectively; and additional *Arabidopsis* LCAT-like sequences LCAT4, LCAT7 and LCAT8 comprising polynucleotides SEQ ID NO: 8, 10 and 11.

Applicant does not describe any other LCAT encoding sequence other than the polynucleotide encoding a human lecithin:cholesterol acyltransferase and the polynucleotides from *Arabidopsis* encoding lecithin:cholesterol acyltransferase-like polypeptide sequences.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of isolated polynucleotides encoding a lecithin:cholesterol acyltransferase-like polypeptide; isolated polynucleotides having at least 70% sequence identity to SEQ ID NO: 4; isolated polynucleotides having at least 10 nucleotides that hybridize under condition of unspecified stringency to SEQ ID NO: 4; isolated polynucleotides encoding SEQ ID NO: 5 with at least one conservative amino acid substitution; isolated polynucleotidse that hybridizes to SEQ ID NO: 4 under conditions of unspecified stringency and encodes a plant lecithin:cholesterol acyltransferase-like polypeptide; or a recombinant construct comprising a regulatory sequence operably linked to a polynucleotide sequence encoding a lecithin:cholesterol acyltransferase-like polypeptide. Applicants only describe the human (SEQ ID NO: 1) and *Arabidopsis* lecithin:cholesterol acyltransferase-like polynucleotide sequences of SEQ ID NO: 2, 4, 6, 8, 10 and 11. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides encoding a lecithin:cholesterol acyltransferase-like polynucleotide; that have at least 70% sequence identity to SEQ ID NO: 4, that encode a polypeptide having at least one conservative amino acid substitution into SEQ ID NO: 5, that hybridize to at least 10 nucleotides of SEQ ID NO:4; that hybridize to SEQ ID NO: 4 and either encode a lecithin:cholesterol acyltransferase-like polypeptide; or recombinant vectors that comprise a polynucleotide encoding a lecithin:cholesterol acyltransferase-like polypeptide. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for polynucleotides encoding a lecithin:cholesterol acyltransferase-like polypeptide, it remains unclear what features identify a lecithin:cholesterol acyltransferase-like polypeptide. Since the genus of polynucleotides encoding lecithin:cholesterol

acyltransferase-like polypeptides from plant or from other sources has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that hybridize with SEQ ID NO: 4 and encode a LCAT-like polypeptide, or hybridize to at least 10 nucleotides of SEQ ID NO: 4, or are which are at least 70% complementary to SEQ ID NO: 4, encompass naturally occurring allelic variants, mutants of SEQ ID NO: 4, as well as sequences encoding proteins having no known LCAT activity or LCAT-like activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides that are at least 70% complementary to SEQ ID NO: 4, that hybridize to SEQ ID NO: 4 and encode a lecithin:cholesterol acyltransferase-like polypeptide, or polynucleotides that hybridize to at least 10 nucleotides of SEQ ID NO: 4 encompassed by the hybridization language or percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115 and 117 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO: 4 encoding a plant lecithin:cholesterol acyltransferase-like polypeptide of SEQ ID NO: 5, recombinant vectors comprising SEQ ID NO: 4, and plants transformed therewith having increased oil content in transformed seeds, does not reasonably provide enablement for any non-exemplified polynucleotide from plants or non-plant sources encoding a lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof; or for non-exemplified polynucleotides which are at least

70% complementary to SEQ ID NO: 4; or for non-exemplified polynucleotide sequences that hybridize to any unspecified portion of at least 10 nucleotides of SEQ ID NO: 4, or for non-exemplified polynucleotides that hybridize to SEQ ID NO: 4 encoding a lecithin:cholesterol acyltransferase-like polypeptide other than SEQ ID NO: 4; or plants transformed with any sequence encoding a lecithin:cholesterol acyltransferase-like polypeptide in sense or antisense orientation producing transformed seeds having an increase in sterol-esters, oil content or sterol content in transformed seeds, or for plants transformed with LCAT2 SEQ ID NO: 4 producing transformed seeds having increased sterol-ester or increased phytosterol content. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Applicant broadly claims an isolated nucleic acid sequence comprising a polynucleotide encoding a plant lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof; an isolated polynucleotide having at least 70% sequence identity to SEQ ID NO: 4; an isolated polynucleotide having at least 10 nucleotides that hybridize under condition of unspecified

stringency to SEQ ID NO: 4; an isolated polynucleotide that hybridizes to SEQ ID NO: 4 under conditions of unspecified stringency and encodes a plant lecithin:cholesterol acyltransferase-like polypeptide; an isolated polynucleotide encoding SEQ ID NO: 5 with at least one conservative amino acid substitution; a recombinant construct comprising a regulatory operably linked to a sequence encoding a lecithin:cholesterol acyltransferase and host cells, plants and progeny and seeds transformed therewith.

Applicant teaches PCR amplification of LCAT1-4 (SEQ ID NO: 2, 4, 6 and 8) using specific primers (page 36-37 of specification); cloning of LCAT 1, 2, 3 and 4 (SEQ ID NO: 2, 4, 6 and 8) into expression and transformation vectors in sense and antisense orientation (pages 40-41 of specification); transformation of *Arabidopsis* plants with a recombinant vector comprising either LCAT 1, 2, 3, or 4, (SEQ ID NO: 2, 4, 6 or 8) (pages 44-45 specification); thin layer chromatography assay for cholesterol ester production (i.e. the activity of a lecithin:cholesterol acyltransferase) in insect cells transformed with a baculovirus expression system comprising LCAT1, 2, 3 or 4 (SEQ ID NO: 2, 4, 6 or 8) showing cholesterol ester production in insect cells transformed with a baculovirus expression system comprising LCAT4 SEQ ID NO: 8 (page 47 specification) and increases in phytosterols in seeds of *Arabidopsis* plants transformed with LCAT4 SEQ ID NO: 8 (pages 45 specification); *Arabidopsis* plants transformed with LCAT3 SEQ ID NO: 6 having a 50% increase in esterified sterols in transformed seeds (page 46 of specification, lines 27-30); and *Arabidopsis* plants transformed with LCAT2 SEQ ID NO: 4 having an increase in oil content in transformed seeds (page 46 lines 1-4 and page 49 specification).

Applicant does not teach baculovirus expression resulting in sterol ester production (i.e. the activity of a lecithin:cholesterol acyltransferase) or phytosterol increases in transformed seeds with any LCAT-like polynucleotide sequence other than LCAT4 (SEQ ID NO: 8); or increases in sterol ester production in seeds transformed with any LCAT-like polynucleotide sequence other than seeds transformed with LCAT3 (SEQ ID NO: 6); or increases in oil production in the seeds transformed with any LCAT-like polynucleotide sequence other than seeds transformed with LCAT2 (SEQ ID NO: 4).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that that have at least 70% sequence identity, or hybridize to SEQ ID NO: 4, or have homology to a human lecithin:cholesterol acyltransferase polynucleotide will encode a lecithin:cholesterol acyltransferase-like polypeptide. The inherent unpredictability in isolation of a homologous sequence encoding the same protein activity is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity showing that a small number of changes to the coding region of a desaturase could account for the functional divergence seen across a range of enzymes involved in fatty acid metabolism (Broun P. *et al.* Science Vol. 282; 13 November 1998, pp. 1315-1317; Abstract lines 4-6 and p. 1317 column 1, lines 37-56). An example of the unpredictability in isolating lecithin:cholesterol acyltransferase-like encoding polynucleotides using a predictive homology based method is made evident in experiments where 4 gene from *Arabidopsis* were identified by homology based prediction and assumed to encode a putative lecithin:cholesterol acyltransferase but resulted in not one of the four genes being identified as a LCAT encoding gene. Moreover, the gene the authors deemed most likely to encode a lecithin:cholesterol acyltransferase showed

phospholipase A1 activity when transformed into a yeast mutant resulting in the accumulation of triacylglycerol (TAG) and fatty acids (FA) but no increases in sterol-esters (SE). (Noiriel A. *et al.* European Journal of Biochemistry, 2004; Vol. 271, pages 3752-3764; see Abstract lines 1-7; cloning of LCAT-like cDNAs on page 3753 in column 2; page 37576 column 2 beginning with line 4; and the Discussion beginning on page 3761 to page 3762 column 1 line 4). Further, it appears that Applicant's elected invention drawn to SEQ ID NO: 4 does not produce phytosterols or esterified sterols when assayed *in vitro* or in the seeds of transformed plants.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified polynucleotide sequences encoding non-exemplfied putative lecithin:cholesterol acyltransferase-like polypeptides and fragments thereof, by producing expression vectors to test for activity and product formation and by transforming plants therewith, in order to identify those polynucleotides that when over-expressed or expressed in antisense orientation would produce plants that yield increased phytosterols, increased oil content, or increases in the amount of esterified sterols in their transformed seeds.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 46-47 and 49-50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed progeny and seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claims 46-47 and 49-50 are drawn to parts such as seeds or progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only two thirds of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants and seeds that are indistinguishable from plants and seeds that would occur in nature. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Federspiel N. *et al.* Gene F21M11.5 as GenBank Accession Number AC003027 December 30, 1998 in light of The Institute for Genomic Research database annotation for Gene F21M11.5; see attachement.

Applicant broadly claims an isolated polynucleotide encoding a plant lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof, wherein the Office interprets lecithin:cholesterol acyltransferase-like to encompass any degree of similarity to any lecithin:cholesterol acyltransferase gene.

Federspiel teaches BAC F21M11, a bacterial cloning vector comprising a cloned segment of *Arabidopsis* chromosome I comprising gene F21M11.5 which encodes a plant lecithin:cholesterol acyltransferase-like polypeptide (see attached TIGR annotation), and that also comprises the plant lecithin:cholesterol acyltransferase-like gene's 5' upstream regulatory promoter sequence and termination sequence (see as GenBank Accession AC003027 and attached sequence reports), and wherein Applicant states for the record on page 31, lines 24-30 of the specification, that SEQ ID NO: 4 encoding SEQ ID NO: 5 is GenBank database accession AC003027, wherein the isolated regulatory sequence comprises a promoter region that is heterologous to the bacterial host cell and is inherently heterologous because it is recombinant, and wherein the isolated 5' upstream regulatory regulatory sequence inherently comprises a combination of constitutive, inducible, developmental or tissue specific promoter expression elements, wherein the 5'X-$(R_1)_n$-$(R_2)_n$-$(R_3)_n$-Y3' formula of Claim 11 having X5' and Y3' as hydrogen is inherently taught by the isolated polynucleotide of the BAC clone in aqueous solution or soluble/hydrated form and wherein the office interprets any nucleic acid of R_1 and R_3 to be a nucleic acid of any length and sequence identity; and wherein a bacterial host cell that comprises the recombinant BAC clone is taught inherently; and thus the reference teaches all the limitations of Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 36, 38, 40 and 41.

All claims are rejected.

Claims 42-50, 76-78, 82, 84, 86, 88, 107, 108, 111, 113, 115 and 117 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest plants transformed with a polynucleotide encoding a lecithin:cholesterol acyltransferase-like polypeptide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis

Russell Kallis Ph.D.
December 10, 2004

Attachment #1

```
  Best Local Similarity   100.0%;  Pred. No. 1.2e-130;
  Matches  243;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy         61 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 120
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Qy        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240

Qy        241 AAG 243
              |||
Db        241 AAG 243


RESULT 4
AX037587
LOCUS       AX037587                3896 bp    DNA     linear   PAT 16-NOV-2000
DEFINITION  Sequence 11 from Patent WO0060095.
ACCESSION   AX037587
VERSION     AX037587.1  GI:11227006
KEYWORDS    .
SOURCE      Arabidopsis thaliana (thale cress)
  ORGANISM  Arabidopsis thaliana
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots;
            rosids; eurosids II; Brassicales; Brassicaceae; Arabidopsis.
REFERENCE   1
  AUTHORS   Banas,A., Stahl,U., Stymne,S., Lenman,M., Ronne,H. and Dahlqvist,A.
  TITLE     A new class of enzymes in the biosynthetic pathway for the
            production of triacylglycerol and recombinant dna molecules
            encoding these enzymes
  JOURNAL   Patent: WO 0060095-A 11 12-OCT-2000;
            BASF PLANT SCIENCE GMBH (DE) ; BANAS ANTONI (PL) ; STAHL ULF (SE) ;
            STYMNE STEN (SE) ; LENMAN MARIT (SE) ; RONNE HANS (SE) ; DAHLQVIST
            ANDERS (SE)
FEATURES             Location/Qualifiers
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                     /mol_type="unassigned DNA"
                     /db_xref="taxon:3702"
ORIGIN

  Query Match             14.8%;  Score 243;  DB 6;  Length 3896;
  Best Local Similarity   100.0%;  Pred. No. 1.2e-130;
  Matches  243;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 60
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Db          1 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 60

Qy         61 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 120

Qy        121 CTATCGGGTATAATCATTCCGGGATTTGCGTCGACGCAGCTACGAGCGTGGTCGATCCTT 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 CTATCGGGTATAATCATTCCGGGATTTGCGTCGACGCAGCTACGAGCGTGGTCGATCCTT 180

Qy        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240
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Db        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240

Qy        241 AAG 243
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Db        241 AAG 243


RESULT 5
AX037606
LOCUS       AX037606                3896 bp    DNA     linear   PAT 16-NOV-2000
DEFINITION  Sequence 30 from Patent WO0060095.
ACCESSION   AX037606
VERSION     AX037606.1  GI:11227020
KEYWORDS    .
SOURCE      Arabidopsis thaliana (thale cress)
  ORGANISM  Arabidopsis thaliana
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots;
            rosids; eurosids II; Brassicales; Brassicaceae; Arabidopsis.
REFERENCE   1
  AUTHORS   Banas,A., Stahl,U., Stymne,S., Lenman,M., Ronne,H. and Dahlqvist,A.
  TITLE     A new class of enzymes in the biosynthetic pathway for the
            production of triacylglycerol and recombinant dna molecules
            encoding these enzymes
  JOURNAL   Patent: WO 0060095-A 30 12-OCT-2000;
            BASF PLANT SCIENCE GMBH (DE) ; BANAS ANTONI (PL) ; STAHL ULF (SE) ;
            STYMNE STEN (SE) ; LENMAN MARIT (SE) ; RONNE HANS (SE) ; DAHLQVIST
            ANDERS (SE)
FEATURES             Location/Qualifiers
     source          1. .3896
                     /organism="Arabidopsis thaliana"
                     /mol_type="unassigned DNA"
                     /db_xref="taxon:3702"
ORIGIN

  Query Match             14.8%;  Score 243;  DB 6;  Length 3896;
  Best Local Similarity   100.0%;  Pred. No. 1.2e-130;
  Matches  243;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 60

Qy         61 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 120
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Db         61 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 120

Qy        121 CTATCGGGTATAATCATTCCGGGATTTGCGTCGACGCAGCTACGAGCGTGGTCGATCCTT 180
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Db        121 CTATCGGGTATAATCATTCCGGGATTTGCGTCGACGCAGCTACGAGCGTGGTCGATCCTT 180

Qy        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240
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Db        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240

Qy        241 AAG 243
              |||
Db        241 AAG 243


RESULT 6
AC003027
LOCUS       AC003027              119914 bp    DNA     linear   PLN 30-OCT-2002
DEFINITION  Arabidopsis thaliana chromosome I BAC F21M11 genomic sequence,
            complete sequence.
ACCESSION   AC003027
VERSION     AC003027.1  GI:4079614
KEYWORDS    HTG.
SOURCE      Arabidopsis thaliana (thale cress)
  ORGANISM  Arabidopsis thaliana
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots;
            rosids; eurosids II; Brassicales; Brassicaceae; Arabidopsis.
REFERENCE   1  (bases 1 to 119914)
  AUTHORS   Federspiel,N.A., Palm,C.J., Conway,A.B., Conn,L., Hansen,N.F.,
            Altafi,H., Araujo,R., Huizar,L., Rowley,D., Buehler,E., Dunn,P.,
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see F21M11.5 on p.3 and TIGR database report

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            Gonzalez,A., Kremenetskaia,I., Kim,C., Lenz,C., Li,J., Liu,S.,
            Luros,S., Schwartz,J., Shinn,P., Toriumi,M., Vysotskaia,V.S.,
            Walker,M., Yu,G., Ecker,J., Theologis,A. and Davis,R.W.
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 119914)
  AUTHORS   Federspiel,N.A., Palm,C.J., Conway,A.B., Kurtz,D.B., Conway,A.R.,
            Au,M., Araujo,R., Buehler,E., Dewar,K., Feng,J., Kim,C., Li,Y.,
            Oji,O., Osborne,B.I., Shinn,P., Sun,H., Toriumi,M., Vyotskaia,V.,
            Yu,G., Ecker,J., Theologis,A. and Davis,R.W.
  TITLE     Direct Submission
  JOURNAL   Submitted (22-OCT-1997) Biochemistry, Stanford University/DNA
            Sequencing and Technology Center, 855 California Avenue, Palo Alto,
            CA 94304, USA
REFERENCE   3  (bases 1 to 119914)
  AUTHORS   Federspiel,N.A., Palm,C.J., Conway,A.B., Conn,L., Hansen,N.F.,
            Altafi,H., Araujo,R., Huizar,L., Rowley,D., Buehler,E., Dunn,P.,
            Gonzalez,A., Kremenetskaia,I., Kim,C., Lenz,C., Li,J., Liu,S.,
            Luros,S., Schwartz,J., Shinn,P., Toriumi,M., Vyotskaia,V.,
            Walker,M., Yu,G., Ecker,J., Theologis,A. and Davis,R.W.
  TITLE     Direct Submission
  JOURNAL   Submitted (30-DEC-1998) DNA Sequencing and Technology Center,
            Stanford University, 855 California Avenue, Palo Alto, CA 94304,
            USA
REFERENCE   4  (bases 1 to 119914)
  AUTHORS   Federspiel,N.A., Palm,C.J., Conway,A.B., Conn,L., Hansen,N.F.,
            Altafi,H., Araujo,R., Huizar,L., Rowley,D., Buehler,E., Dunn,P.,
            Gonzalez,A., Kremenetskaia,I., Kim,C., Lenz,C., Li,J., Liu,S.,
            Luros,S., Schwartz,J., Shinn,P., Toriumi,M., Vyotskaia,V.,
            Walker,M., Yu,G., Ecker,J., Theologis,A. and Davis,R.W.
  TITLE     Direct Submission
  JOURNAL   Submitted (30-JAN-1999) DNA Sequencing and Technology Center,
            Stanford University, 855 California Avenue, Palo Alto, CA 94304,
            USA
COMMENT     On Dec 30, 1998 this sequence version replaced gi:2734094.
            Bases 1-9262 of clone F21M11 overlap with bases 68998-78259 of
            'TAMU' BAC clone F20D22 (AC002411) and bases 119525-119914 of clone
            F21M11 overlap with bases 1-389 of 'TAMU' BAC clone F21B7
            (AC002560).
            e-mail for correspondence: arab@sequence.stanford.edu
            Genes with similarity to proteins in the databases are described as
            'putative', '-like' or 'similar to'.  Genes that have EST
            similarity but no significant protein similarity are described as
            'unknown proteins'.  Genes that are annotated based only on gene
            prediction software are described as 'hypothetical proteins'.
            The software programs used to predict genes include:  Grail
            (Informatics Group, Oak Ridge National Laboratory,
            http://compbio.ornl.gov/section/index.html), GENSCAN (Chris Burge,
            http://gnomic.stanford.edu/~chris/GENSCANW.html), Fexa (V.Solovyev
            & A.Salamov, Sanger Centre,  http://genomic.sanger.ac.uk/), and
            NetPlantGene (S.M. Hebsgaard, et al., CBS, Technical University of
            Denmark,http://www.cbs.dtu.dk/NetPlantGene.html).
FEATURES             Location/Qualifiers
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                     /organism="Arabidopsis thaliana"
                     /mol_type="genomic DNA"
                     /cultivar="Columbia"
                     /db_xref="taxon:3702"
                     /chromosome="I"
                     /clone="F21M11"
     misc_feature    1. .9262
                     /note="overlap with bases 68998-78259 of 'IGF' BAC clone
                     F21M11."
     misc_feature    1. .7000
                     /note="Proteins in this region are annotated in the F21M11
                     entry, AC002411."
     gene            7684. .10913
                     /gene="F21M11.1"
     CDS             join(7684. .7866,7965. .8027,8122. .8160,8250. .8381,
                     8458. .8728,8875. .9893,10003. .10256,10344. .10410,
                     10501. .10551,10685. .10781,10885. .10913)
                     /gene="F21M11.1"
                     /note="Hypothetical protein"
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                     /protein_id="AAD10665.1"
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                     VRRNGERGLAMTVYNNASPSSSSRLSMEPEEVPPMVLLPAHPMETKVSEASALVILND
                     EPNIDHKPVISDTGNCSAPMLEMGKSNIHVQEWDWETKDILNDTTAMDVSPSSAIGES
                     SEHKVAAASVELASSTSGEAKICLSFAPATGETTNLHLPSMEDLRRAMEEKCLKSYKI
                     VHPEFSVLGFMKDMCSCYIDLAKNSTSQLLETETVCDMSKAGDESGAVGISMPLVVVP
                     ECEISGDGWKAISNMKDITAGEENVEIPWVNEINEKVPSRFRYMPHSFVFQDAPVIFS
                     LSSFSDEQSCSTSCIEDCLASEMSCNCAIGVDNGFAYTLDGLLKEEFLEARISEARDQ
                     RKQVLRFCEECPLERAKKVEILEPCKGHLKRGAIKECWFKCGCTKRCGNRVVQRGMHN
                     KLQVFFTPNGKGWGLRTLEKLPKGAFICEYIGEILTIPELYQRSFEDKPTLPVILDAH
                     WGSEERLEGDKALCLDGMFYGNISRFLNHRCLDANLIEIPVQVETPDQHYYHLAFFTT
                     RDIEAMEELAWDYGIDFNDNDSLMKPFDCLCGSRFCRNKKRSTKTMQILNKA"
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                     /gene="F21M11.2"
     mRNA            join(13033. .13488,13717. .13926,14139. .14514)
                     /gene="F21M11.2"
     CDS             join(13061. .13488,13717. .13926,14139. .14316)
                     /gene="F21M11.2"
                     /note="Similar to acid phosphatase; Location of ESTs
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     CDS             complement(join(14567. .14641,14787. .15831,15906. .16006,
                     16327. .16362))
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                     /gene="F21M11.4"
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                     20188. .20238))
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                     FESEYDAANHTPESYTEQAAKNVRDITASEQPSNAARKRICGDSFIQESSPNPKTQDP
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                     WDYEDFLLLCPAHSSVKFPNEKSGHRVSRAEPLPKINPAELCSLEQTPAFTKELVLCG
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                     GEEVTIIWQRANDAEALASQTGSRLVGHTWVLESIAGYKLHPVIG"
     gene            20752. .24647
                     /gene="F21M11.5"
     CDS             join(20752. .20994,21362. .21497,21596. .21740,21825. .21994,
                     22102. .22178,22542. .22758,22920. .23064,23343. .23442,
                     23599. .23693,24021. .24072,24227. .24298,24441. .24647)
                     /gene="F21M11.5"
                     /note="Hypothetical protein"
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                     IIPGFASTQLRAWSILDCPYTPLDFNPLDLVWLDTTKLLSAVNCWFKCMVLDPYNQTD
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                     KWLDQHIHAYFAVGAPLLGSVEAIKSTLSGVTFGLPVSEGTARLLSNSFASSLWLMPF
                     SKNCKGDNTFWTHFSGGAAKKDKRVYHCDEEEYQSKYSGWPTNIINIEIPSTSARELA
                     DGTLFKAIEDYDPDSKRMLHQLKKYVPFFVIRNIAHRSSLAGFLLYHDDPVFNPLTPW
                     ERPPIKNVFCIYGAHLKTEVGYYFAPSGKPYPDNWIITDIIYETEGSLVSRSGTVVDG
                     NAGPITGDETVPYHSLSWCKNWLGPKVNITMAPQILIGKIKQQPEHDGSDVHVELNVD
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     CDS             28007. .28465
                     /gene="F21M11.6"
                     /note="Unknown protein; Location of ESTs 203I24T7,
                     gb|H76794 and 203I24XP, gb|AA605510"
                     /codon_start=1
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                     /db_xref="GI:4204289"
                     /translation="MNTKTMRLPPRRVLTADKRKERDAFISSVTDNPPEIAKFPSPPP
                     KLVPPPVNPISKKSSTAAAEPIGSNQLMLAGYLSHEYLTQGTLFGEQWNQARAQAESS
                     KIKPSHTVEPAEECEPKRKRYREVANLLRSDGAQLPGIVNPAQLARFLKL"
     gene            complement(29264. .32033)
                     /gene="F21M11.7"
     CDS             complement(join(29264. .31015,31312. .31414,31484. .31587,
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Query Match 14.8%; Score 243; DB 8; Length 119914;
Best Local Similarity 100.0%; Pred. No. 1.1e-130;
Matches 243; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 60
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Db      20752 ATGGGAGCGAATTCGAAATCAGTAACGGCTTCCTTCACCGTCATCGCCGTTTTTTTCTTG 20811

Qy         61 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 120
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Db      20812 ATTTGCGGTGGCCGAACTGCGGTGGAGGATGAGACCGAGTTTCACGGCGACTACTCGAAG 20871

Qy        121 CTATCGGGTATAATCATTCCGGGATTTGCGTCGACGCAGCTACGAGCGTGGTCGATCCTT 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      20872 CTATCGGGTATAATCATTCCGGGATTTGCGTCGACGCAGCTACGAGCGTGGTCGATCCTT 20931

Qy        181 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      20932 GACTGTCCATACACTCCGTTGGACTTCAATCCGCTCGACCTCGTATGGCTAGACACCACT 20991

Qy        241 AAG 243
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Db      20992 AAG 20994
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RESULT 7
AX090361
LOCUS       AX090361                44 bp    DNA     linear   PAT 21-MAR-2001
DEFINITION  Sequence 54 from Patent WO0116308.
ACCESSION   AX090361
VERSION     AX090361.1  GI:13444222
KEYWORDS    .
SOURCE      synthetic construct
  ORGANISM  synthetic construct
            artificial sequences.
REFERENCE   1
  AUTHORS   Lassner,M. and van Eenennaam,A.
  TITLE     Plant sterol acyltransferases
  JOURNAL   Patent: WO 0116308-A 54 08-MAR-2001;
            MONSANTO COMPANY (US)
FEATURES             Location/Qualifiers
     source          1. .44
                     /organism="synthetic construct"
                     /mol_type="unassigned DNA"
                     /db_xref="taxon:32630"
                     /note="Synthetic oligonucleotide primer"
ORIGIN
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Query Match 1.6%; Score 27; DB 6; Length 44;
Best Local Similarity 100.0%; Pred. No. 0.0027;
Matches 27; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 ATGGGAGCGAATTCGAAATCAGTAACG 27
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Db         18 ATGGGAGCGAATTCGAAATCAGTAACG 44
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RESULT 8
AX090362/c
LOCUS       AX090362                40 bp    DNA     linear   PAT 21-MAR-2001
DEFINITION  Sequence 55 from Patent WO0116308.
ACCESSION   AX090362
VERSION     AX090362.1  GI:13444223
KEYWORDS    .
SOURCE      synthetic construct
  ORGANISM  synthetic construct
            artificial sequences.
REFERENCE   1
  AUTHORS   Lassner,M. and van Eenennaam,A.
  TITLE     Plant sterol acyltransferases
  JOURNAL   Patent: WO 0116308-A 55 08-MAR-2001;
            MONSANTO COMPANY (US)
FEATURES             Location/Qualifiers
     source          1. .40
                     /organism="synthetic construct"
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ORIGIN
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Query Match 1.6%; Score 26; DB 6; Length 40;
Best Local Similarity 100.0%; Pred. No. 0.011;
Matches 26; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy       1616 GGGAGCTTGATAAAAGTGGGTATTAA 1641
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Db         40 GGGAGCTTGATAAAAGTGGGTATTAA 15
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RESULT 9
AF493159
LOCUS       AF493159                2609 bp    mRNA    linear   PLN 02-DEC-2002
DEFINITION  Medicago truncatula putative phosphatidylcholine acyltransferase
            mRNA, complete cds.
ACCESSION   AF493159
VERSION     AF493159.1  GI:25992000
KEYWORDS    .
SOURCE      Medicago truncatula (barrel medic)
  ORGANISM  Medicago truncatula
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots;
            rosids; eurosids I; Fabales; Fabaceae; Papilionoideae; Trifolieae;
            Medicago.
REFERENCE   1  (bases 1 to 2609)
  AUTHORS   Benveniste,P., Bouvier-Nave,P., Schaller,H. and Noiriel,A.
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